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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,448	03/05/2001	Santu Bandyopadhyay	A34065	2808
21003	7590	11/20/2003	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			EWOLDT, GERALD R	
			ART UNIT	PAPER NUMBER

1644

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/800,448

Applicant(s)
Bandyopadhyay et al.

Examiner
G.R. Ewoldt, Ph.D.

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 28, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-33 is/are pending in the application.
- 4a) Of the above, claim(s) 32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 703 6) ☐ Other:

DETAILED ACTION

1. Newly submitted Claims 32 and 33 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the invention under examination comprises a method for producing Langerhans' (immature) dendritic cells (DCs). Newly submitted claims 32 and 33 recite a method for producing mature DCs. Said methods are patentably distinct.

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Claims 32 and 33 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Claims 14-27, and newly added Claims 28-31 are pending and being acted upon.

3. In view of Applicant's amendments all previous rejections under the second paragraph of 35 U.S.C. 112 have been withdrawn.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 14-27 and newly added Claims 28-31 stand/are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record as set forth in the paper mailed 4/23/03.

Applicant's arguments, filed 7/28/03, have been fully considered but they are not persuasive. Applicant argues that "the Examiner has failed to satisfy the burden to establish a reasonable basis to question the enablement provided for the claimed invention," specifically, "Applicants respectfully assert that the Examiner has failed to satisfy the burden of showing that one of ordinary skill in the art could not produce cells highly reactive to anti-HLA-DR, anti-CD40, and anti-CD86 while having only weak reactivity to anti-CD1a, anti-CD1b, CD80 and CD83."

Applicant has apparently misunderstood the basis for the rejection, it is the Examiner's position that the specification fails to sufficiently demonstrate that the method of the instant claims would result in a Langerhans' cell, i.e., an immature DC (as set forth by Steinman, *Fundamental Immunology*, Paul, ed. 1999).

Applicant argues that "Applicants are entitled to be their own lexicographer and have defined the terms "dendritic Langerhans type cells" and "Langerhans-type dendritic cell" to mean cells with the features described, inter alia, at page 8, lines 15-22 and figure 2".

Applicant is advised that the Examiner has found no specific definitions for either term in the specification. Accordingly, the term Langerhans' cell has been given its usual meaning as set forth above.

Applicant argues "Applicants further assert that art does not recognize the bright line of demarcation between immature and mature dendritic cells. Dendritic cells possess a heterogeneous haemopoietic lineage that, together with the culture conditions, influences the morphology and immunological reactivity of the resulting cells."

The Examiner does not know to what "bright line" Applicant is referring, however, Langerhans' cells are defined as comprising certain properties, while mature DCs are defined as comprising others (as set forth previously). The cells that result from the method of the instant claims seem to comprise neither type (as set forth previously).

It remains the Examiner's position that the specification fails to teach one of skill in the art how to make a Langerhans' cell (as it is known in the art). Thus, the rejection has been maintained.

6. The following are new grounds of rejection necessitated by Applicant's amendment.

7. Claims 14-22, 27, and newly added Claims 28-29 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed (note that the new matter portion of the claims is underlined), specifically: a method comprising "a medium containing platelets" that results in a Langerhans' cell.

Applicant indicates that support for the new limitation can be found at pages 1-3 of the specification. Upon careful review of the specification no support for the broadening of the instant invention, i.e., the use of platelets of any species to produce Langerhans' cells of any species.

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. **Please Note:** inquiries of a general nature or relating to the status of this application should not be directed to the Examiner but rather should be directed to the Technology Center 1600 Customer Service Center at (703) 308-0198.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
November 17, 2003



G.R. EWOLDT, PH.D.
PRIMARY EXAMINER